greater concentration of solute on one side [and] second, the solute particle cannot pass through the membrane, whereas the solvent particles can." See MERRILL CHEMISTRY, p. 533 (McGraw-Hill 1998) attached hereto. Osmotic cells are the preferred method of moving solvent in certain applications because the movement of the solvent can create negative pressure on the side of the membrane vacated by the solvent. This pressure is achieved and maintained by the membrane in combination with a fluid (liquid or air) impermeable housing about the osmotic cell.

Applicant uses an osmotic cell in a unique way. It is known that in treating wounds, it is advantageous to remove wound fluid which may contain toxins or other elements that are not conducive to healing. Additionally, the absence of excess fluid helps the healing process. Further, it has been shown that wounds heal better in a negative pressure environment. Applicant uses an osmotic cell to achieve these purposes in a way that doesn't require tethering to a vacuum source, a remote wound fluid receptacle, or other source or apparatus removed from the wound site. Applicant's device removes the wound fluid and stores it a chamber at the wound site, but separate and no longer in communication with the wound. Further, the chamber doesn't lose its ability to retain wound fluid due to a saturation level component.

As shown in Fig. 3A, of the above-identified application, a housing 102 incorporates an osmotic cell 120 that includes an osmotic membrane (such as Nafion® or any cation or anion membrane) in communication with antimicrobial sponge 106 placed within cavity 130 of housing 102 of device 10. *See* page 14, lines 9-14. Applicant's osmotic cell 120 uses a saturated salt solution/or salt pellet 122 in chamber 124 to create the difference in solvent concentration on the opposite side of the membrane from the wound fluid. Accordingly, fluids from sponge are

pulled into osmotic cell 120 and stored in chamber 124. In the process, a vacuum is created within cavity 130 over the wound. Applicant's device is configured as a disposable patch.

The Karami Patent

The purpose of Karami is to provide an adhesive dressing that will maintain its adhesive seal over the wound, even under increased pressure generated by wound fluid, to prevent infection by ambient contaminants. Col. 1, lines 5-13. Karami teaches a system of fabrics with different densities to absorb wound fluid into a secondary fabric dressing that can act as a reservoir. The wound fluid is drawn to the reservoir fabric by wicking. Col. 7, lines 45-49. The fabrics are covered by a thin conformable air-permeable sheet material. Col. 5, line 1-4; Col. 5 line 67 – Col. 6 line 14. Karami teaches that air removal is necessary to increase the absorbency, and thus the wicking, of the fabrics. Id.

Karami recognized that fabric reservoirs will saturate and that the secondary dressing that acts as a reservoir will need to be replaced. Col. 5, lines 63-65; Col. 7, lines 58-69. Karami also desires a removable second dressing to allow for observation of the healing process. Id. Accordingly, Karami teaches release coatings. Col. 8, lines 3-47.

The Theeuwes Patent

The purpose of Theeuwes is to provide a controlled drug delivery system. Theeuwes does not deal with wounds. Theeuwes also does not teach removing fluid, but rather uses an osmotic pump to dispense fluid to the skin. *See* Theeuwes Abstract. In Theeuwes, water is continuously imbibed to form a solution which is pumped to the skin. The solution is free to spread over the surface of the skin layer for transdermal absorption. Col.4, line 62-Col. 5, line 1.

The Zamierowski Publication

The purpose of Zamierowski is to provide a wound therapy and tissue management system. The Zamierowski uses various assemblies and attachments to remote sources and apparatuses to collect and deliver fluids. *See* paragraph 17. Zamierowski's components are covered by a drape with openings for inflows and outflows. *See* paragraph 45 and Figures 2-6. Zamierowski uses a vacuum to remove fluid through tubing to a remote collector. *See* paragraphs 43, 54, 57, 61, and 65 and the Figures. The openings leave the covering permeable or at least semipermeable. *See* paragraph 91.

Section 103 Rejection

Applicant respectfully disagrees that the references cited by the examiner constitute a proper obviousness rejection under Section 103. As examiner is aware, 35 U.S.C. 103 authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 706.02(j).

There is no motivation to combine the references.

There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet,* 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper.). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

There is nothing in any one of the references to explicitly combined the references and Examiner and not noted any. Accordingly, the suggestion must be implicit. The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab,* 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee,* 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Karami and Zamierowski address problems in wound dressing and wound therapy respectively. Theeuwes does not deal with wounds at all. Theeuwes deals with fluid delivery. Theeuwes provides additional fluid to the skin for transdermal absorption. Excess fluid is contrary to the purposes of wound dressings and therapy. Thus, one of skill in the art would not be motivated to combine the teachings of Theeuwes with Karami and Zamierowski.

Karami and Theeuwes address a localized application whereas Zamierowski contemplates monitoring and remote collection, suction sources, and collection sites. Zamierowski would not seek to utilize the teachings of Karami, which teaches a localized band aid ® not a therapy system. Zamierowski would also have no use for the solution delivery system of Theeuwes.

Karami and Zamierowski teach permeable or semipermeable housings. Theeuwes operates by use of an impermeable housing. Karami and Zamierowski specifically teach the need for air egress or openings for inflows and outflows. Neither Karami nor Zamierowski would look to the teachings of Theeuwes to help solve the problems they address. Thus, there is not suggestion to combine these references.

The mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not

require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.). See also *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992) (flexible landscape edging device which is conformable to a ground surface of varying slope not suggested by combination of prior art references).

Finally, if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Although Karami and Zamierowski both reference wounds, it is conceivable that Karami could be modified to provide wound therapy. However, there would be no motivation to do it. Karami is meant to be a disposable, untethered, and less expensive dressing to keep the wound dry. Adding the teachings of Zamierowski to Karami would totally defeat the purpose of Karami. Similarly, by removing the hosing, monitoring capabilities, and assemblies of Zamierowski, you could conceivably get to Karami, however, you would lose the ability to conduct therapy, which is the purpose of Zamierowski.

There is no reasonable expectation of success.

For the reasons set forth above, there is no reasonable expectation of success by combining the references. As mentioned, combining the absorbing fabric of Karami with the fluid delivery of Theeuwes would frustrate the purposes of both patents and not lead to any

expectation of a successful combination. Similarly, adding the monitoring and therapy tethers of Zamierowski to the simple fabric layers of Karami would not provide a reasonable expectation of success. Additionally, one would not expect success by combining Zamierowski, which requires permeable or semipermeable housings, with Theeuwes, which requires an impermeable housing.

The combined references do teach every element of Applicant's claimed invention.

Even if the combination of these references were appropriate, they do not teach every element of Applicant's claimed invention. Applicant teaches the use of an osmotic cell for removing fluid from the sponge and transporting it into a chamber. Karami does not mention an osmotic cell. Karami does not teach the recognized components of an osmotic cell, including a semipermeable membrane with a solvent concentration difference on either side of the membrane. Theeuwes does not teach the use of an osmotic cell for removing fluid from the sponge (claim 17) or cavity (claim 24) and transporting it into a chamber. Theeuwes doesn't teach a sponge. Additionally, Theeuwes uses an osmotic pump to drive fluid from a reservoir, not to pull fluid away to a chamber. Zamierowski also does not teach an osmotic cell. Zamierowski mentions osmosis in passing, but nowhere does Zamierowski teach the elements of an osmotic cell, including an impermeable membrane in combination with different solvent concentration on the appropriate sides of the membrane.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (801-978-2186) to facilitate prosecution of this application.

Respectfully submitted,

ASHOK V. JOSHI

By his Representative,

Date May 31, 2006 By _____
David Fonda
Reg. No. 39,672

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Patent and Trademark Office via hand delivery addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 31 day of May, 2006.

David Fonda

Name

Signature